REMARKS

Reconsideration is respectfully requested in view of Applicants' amendments and remarks herein.

The claims under consideration are claims 1-11.

Generic claims 1 and 11 are directed to a clear aqueous ceramide composition and a method for preparing a clear aqueous composition containing the ceramide, respectively. In each instance, the linking language "consisting essentially of" has been utilized and the clear aqueous solution contains 1.0 to 5.0 % by weight of a ceramide as represented by formula (I) of those claims. Claim 11, the third generic claim in the application, is a lipid composition usable for preparing the clear aqueous ceramide composition of claim 1. The lipid composition consists essentially of the clear aqueous ceramide composition of claim 1 ingredients, in the same proportions, without the water.

The Examiner has set forth a rejection of all claims under 35 U.S.C. § 103(a) as being obvious to one of ordinary skill in the art over Nakamura et al. in combination with Kaneko et al., two references previously considered, but not in this relationship.

The Examiner submits that Nakamura discloses a transparent cosmetic composition comprising a ceramide, a nonionic surfactant, an ionic surfactant and an aqueous medium. The Examiner states that Nakamura does not teach the specific ceramides of Applicants' claims, that is, the ceramides of the formula (I). In fact, as has been previously pointed out during earlier prosecution, the compound that the Examiner describes as a ceramide is set forth in Nakamura as an amphiphatic lipid, and is not a true ceramide.

In any event, the Examiner goes on to consider the Kaneko et al. secondary reference and submits that it teaches a protective agent for skin and hair comprising a specific ceramide, a surface active agent, a higher fatty acid and a lipid. The Examiner submits that the specific ceramides recited in the prior art of Kaneko et al. appear to have the same structure as the ceramides recited in the instant claims.

Also noting that neither Nakamura nor Kaneko expressly teach the exact concentration ranges recited in the instant claims, and in this regard the Examiner is requested to note the amendments made to claims 1 and 7, the Examiner goes on to submit that it would be obvious to a person skilled in the art to vary the amounts of ingredients and to substitute one ceramide for another similar ceramide. The Examiner submits that there is no criticality with respect to the claim concentrations. The Examiner submits that Applicants have also not shown unexpected results with respect to the specific selection of ceramides.

As explained in the Background of the Invention section of the present application, ceramides are highly crystalline high-melting compounds having extremely low solubility in most oil-soluble or water-soluble bases (solvents) for cosmetics and as a result it has been difficult to formulate ceramides into stable preparations in the form of clear solutions. See page 2, beginning at line 9 of the present application.

The inventors then go on to discuss specific prior art references, and note Japanese patent 3008212 of Nakamura in the last paragraph of the Background of the Invention section of the application, beginning at page 3, line 12. Concerning the requirement of an ionic surface active

agent in this prior art reference, Applicants note that "In addition, there is a fear of skin irritation due to the ionic surface active agent which is not preferred for cosmetics." page 3, lines 17-19.

Nakamura essentially requires the "ionic surface active agent" in order to prepare a clear composition. Nakamura's claim 1 is directed to a cosmetic composition including 0.05 to 30% by weight of a nonionic surfactant (column 5, line 60). The examples in Nakamura use 0.1 to 0.75% of ionic surface active agent. (Examples 21 and 11).

As a result of the requirement of the ionic surface active agent in Nakamura in order to provide a transparent or translucent cosmetic and in consideration of the potential skin irritation, the skilled artisan would never consider combining the ceramide of Kaneko as a skin protection and/or hair protection agent in the composition of Nakamura or to substitute it into the composition of Nakamura. Obviously, one would not take a protective agent from one reference and substitute it into a formulation from another reference which contains a required component which is considered a potential skin irritant.

Thus, there will be, if anything, a total lack of motivation to make the substitution as suggested in the Office Action.

Indeed, if the skilled artisan did consider the substitution as suggested by the Examiner, that is, the replacement of the amphiphatic lipid of Nakamura with the ceramide of Kaneko, the skilled artisan would need to also consider some mechanism by which to eliminate the ionic surface active agent of Nakamura. If anything, such a consideration would involve the realm of invention as opposed to a routine substitution. For this additional reason, Applicants must

AMENDMENT UNDER 37 C.F.R. § 1.111 U.S. APPLN. NO. 09/848,225

strenuously submit that the Examiner is simply not evaluating the prior art compositions as one of ordinary skill in the art would do.

Kaneko describes the solubility of the Kaneko ceramide in Table 1 at page 11 of Kaneko. There, it is seen that solubility in ethanol is 0.1%. Contrary to the low solubility of Kaneko, the present inventors have discovered a mechanism whereby the ceramide can be dissolved in an aqueous solvent, maintaining transparency, in an amount of 1 - 5% by weight. Certainly, it is believed that the Examiner would agree that the skilled artisan would consider that the solubility of a ceramide in an alcoholic solvent such as ethanol would be much higher than a solubility in an aqueous solvent. As a result, the skilled artisan would not consider trying to obtain transparency by using ceramide of Kaneko, which is dissolved in ethanol only at the 0.1% level. Present inventors have unexpectedly achieved an aqueous transparent composition without worrying about skin irritation, without using an ionic surface active agent, with a high amount of ceramide therein. This invention was thereby achieved by the mixing of components (A) to (C) as defined in the present claims in the relative proportions as set forth therein.

Early indication of allowability is respectfully requested. If any minor points remain prior to Notice of Allowance, the Examiner is respectfully requested to contact the undersigned at the below listed phone number.

AMENDMENT UNDER 37 C.F.R. § 1.111 U.S. APPLN. NO. 09/848,225

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

Registration No. 24,835

SUGHRUE MION, PLLC

Telephone: (202) 293-7060 Facsimile: (202) 293-7860

washington office 23373 customer number

Date: September 8, 2003